

PTO/SB/21 (09-04)

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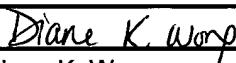
Total Number of Pages in This Submission

Application Number	09/869,282
Filing Date	June 18, 2002
First Named Inventor	SIRIMANNE
Art Unit	3737
Examiner Name	Casler
Attorney Docket Number	032,290-092

### ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
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<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): <ul style="list-style-type: none"> <li>- Copies of 46 references</li> <li>- Copies of 4 search reports</li> <li>- Receipt verification postcard</li> </ul>
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<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		
Remarks		

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	O'MELVENY & MYERS LLP		
Signature			
Printed name	Diane K. Wong		
Date	June 13, 2006	Reg. No.	54,550

### CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

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Typed or printed name	Cynthia B. Pacheco	Date	June 13, 2006

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Patent  
Attorney Docket No. 032,290-092

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

**SIRIMANNE**

Serial No.: 09/869,282

Filed: June 18, 2002

For: DEVICES AND METHOD FOR  
MARKING OF A BIOPSY CAVITY

Group Art Unit: 3737

Examiner: Casler

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with 37 CFR §§ 1.97 and 1.98, the items identified in this Information Disclosure Statement ("IDS") are brought to the attention of the Office. The items are listed on the attached form PTO-SB/08. Also attached are copies of four search reports for related applications. Please note that the references identified on the search reports may have been cited in previously submitted Information Disclosure Statements.

The items identified in this IDS may or may not be "material" pursuant to 37 CFR § 1.56. The submission thereof by Applicant is not to be construed as an admission that any such patent, publication or other information referred to therein is material or considered to be material (37 CFR § 1.97(h)), or even qualifies as "prior art" under 35 USC § 102 with respect to this invention unless specifically designated by Applicant as such.

In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to

**CERTIFICATE OF MAILING (37 C.F.R. §1.8)**

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class mail in an envelope addressed to the Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

June 13, 2006  
Date of Deposit  
NB1:679991.1

*Cynthia B. Pacheco*

Cynthia B. Pacheco

the Patent and Trademark Office in U.S. Patent Application No. 09/285,329, filed on April 2, 1999, now U.S. Patent No. 6,356,782, issued on March 12, 2002.

**INFORMATION DISCLOSURE STATEMENT FILING PROVISION:**

This IDS is believed to be timely in that it is being submitted under 37 CFR § 1.97(b), that is (1) within three months of the filing date of the application, which is not a continued prosecution application filed under § 1.53(d); or (2) within three months of entry of the national stage as set forth in 37 CFR § 1.491; or (3) before the mailing of a first Office action on the merits; or (4) before the mailing of a first Office action after filing a request for continued examination under § 1.114. Thus, no fee is required.

However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and charge the fee due under 37 CFR § 1.17(p) to the deposit account referenced below.

However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and a statement under 37 CFR § 1.97(e) is included below, thus no fee is required.

This IDS is being submitted under 37 CFR § 1.97(c), that is after mailing of a first Office action on the merits, but before a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311.

The fee due under 37 CFR § 1.17(p) is submitted herewith.

A statement under 37 CFR § 1.97(e) is included below, thus no fee is required. In the event that this IDS is not received before a Final Action or a Notice of Allowance, then Applicant respectfully requests that the Office consider the filing of these papers to be submitted under 37 CFR § 1.97(d) and charge the fee due under 37 CFR § 1.17(p) to the deposit account below.

This IDS is being submitted under 37 CFR § 1.97(d), that is after a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311, but before payment of the issue fee. A statement under 37 CFR § 1.97(e) is included below. The fee due under 37 CFR § 1.17(p) is submitted herewith.

**Statement Under 37 CFR § 1.97(e):**

Each item contained in this IDS was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS.

No item contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this statement after

making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this IDS.

Some references are in a language other than the English language. A concise explanation of relevance is given below.

**DE 4330958**

The invention relates to novel microparticles containing active compound, which, additionally to the active compound(s), contain at least one gas or gaseous phase, media (microparticulate systems) containing these particles, their use for the ultrasonically controlled in vivo release of active compound and process for the production of the particles and media.

**DE 4403789**

The invention relates to the use of coloured NMR, X-ray or possibly dye-containing ultrasonic-image-producing substances for marking bodily tissues.

**DE 935625**

This reference discloses a biopsy instrument and method for acquiring subcutaneous biopsies and for removing lesions.

**FR 2714284**

The prosthesis consists of a circular component made from a supple material with a shape memory effect, able to occupy three different positions. In the first position (2) it is extended lengthwise to form a small cylinder which can be introduced through a catheter, with its proximal end closed by a valve (4). In a second position the two compartments (8,10) are inflated separately so that they are deployed on opposite sides of the ruptured wall, while in the third position the compartments are squeezed together to form a double patch on the wall. The prosthesis has a radio-opaque marker (6) between the two compartments which allows its progress through the patient's body to be monitored.

**EP 0146699**

The implants consisting of contrast body (1) and anchoring body (2) are fixed positionally secure in the bone with the aid of a structure of the anchoring body (2) and thus form, in the bone, immovable reference points for the measurement of X-ray pictures.

**WO 98/43090**

Especially nodal conditions and tumour size, histological type, degree of differentiation and receptor condition are used nowadays for the prognosis and further planning of patients with carcinoma of the

breast. Emphasis is placed on evaluation of the condition of the axillary lymph node. Patients with a negative axillary lymph node condition generally receive no after-treatment, as their prognosis is better; yet 30 % of these patients suffer relapses. The method proposed by this invention should make it possible to determine the patient's risk of recidivation. In accordance with the invention, the invention makes it possible to predict the further evolution of patients with carcinoma of the breast by means of a qualitative or quantitative determinatin of T1 protein and/or T1-mRNA is sample material taken from the patients.

**WO 98/52616**

The invention relates to a pharmaceutical preparation containing at least one particulate, vesicular or polymer diagnostic reagent combined with at least one nonsteroidal antirheumatic agent and/or thrombocyte-agglutination inhibitor. The invention also describes the possibility of improving the concentration and homogeneity of contrast media distribution of particles, vesicles or polymers in pharmaceutical preparations in lymph nodes by combining the particular vesicular or polymer contrast media with non steroidal antirheumatic agents or thrombocyte-agglutination inhibitors. This combination results in an extended residence time in the vascular area (longer blood half time period) so that the use thereof as contrast media in diagnostic representation of the vascular system is also improved. In order to improve the diagnostic value of iron oxides as a result of improved concentration in lymph nodes or extended blood half time periods, it makes little difference if the non-steroidal antirheumatic agent of the thrombocyte-agglutination inhibitor is administered shortly before applying the contrast medium or together with a pharmaceutical preparation. According to the invention, the application can occur in an inverse order.

**PAYMENT AND/OR AUTHORIZATION TO CHARGE FEES:**

A check in the amount of \$180.00 is enclosed for the above fee(s).  
 Please charge \$180.00 to Deposit Account No. **50-2862** for the above fee(s).

The Commissioner is authorized to charge any fees required by the filing of these papers, and to credit any overpayment to O'Melveny and Myers' Deposit Account No. **50-2862**.

Respectfully submitted,

O'MELVENY & MYERS LLP

Dated: June 13, 2006

By: Diane K. Wong  
Diane Wong  
Reg. No. 54,550  
Attorneys for Applicant

DKW/  
O'MELVENY & MYERS LLP  
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Newport Beach, CA 92660-6429  
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Substitute for form 1449A-PTO

JUN 16 2006

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use as many sheets as necessary)

## Complete If Known

Application No.	09/869,282
Filing Date	June 18, 2002
First Named Inventor	Sirimanne
Art Unit	3737
Examiner Name	Casler
Sheet	1
of	4
Attorney Docket No.	032,290-092

## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Document No.	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	1.	us-5,183,463	02/1993	Debbas	
	2.	us-6,749,554	09/2004	Snow	

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code (if known)				
	3.	DE 0935625	11/1955			
	4.	GB 2132091	07/1984			
	5.	EP 0146699	07/1985			
	6.	EP 0255123	02/1988			
	7.	EP 0293605	12/1988			
	8.	EP 0350043	01/1990			
	9.	WO 9015576	12/1990			
	10.	EP 0481685	04/1992			
	11.	EP 0534696	03/1993			
	12.	WO 9319803	10/1993			
	13.	DE 4330958	03/1995			
	14.	FR 2714284	06/1995			
	15.	DE 4403789	08/1995			
	16.	WO 9608208	03/1996			
	17.	EP 0769281	04/1997			
	18.	WO 9809247	03/1998			
	19.	WO 9843090	10/1998			
	20.	WO 9847430	10/1998			
	21.	WO 9852616	11/1998			
	22.	WO 9852617	11/1998			

Examiner  
SignatureDate  
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Sheet	2	of	4	Attorney Docket No.	032,290-092

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		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code (if known)				
23.		WO 9911196	03/1999			
24.		WO 9925248	05/1999			
25.		WO 9946284	09/1999			
26.		WO 9966834	12/1999			
27.		WO 0024320	05/2000			
28.		WO 0032253	06/2000			
29.		WO 0038579	07/2000			
30.		WO 0045854	08/2000			
31.		WO 0045858	08/2000			
32.		WO 0100101	01/2001			

<b>NON PATENT LITERATURE DOCUMENTS</b>						
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s) volume-issue number(s), publisher, city and/or country where published				T <sup>2</sup>
	33.	ALESCH, et al., "Marking of the Stereotactic Target Point by a Radiopaque Silicone Sphere," <i>Acta Neurochirurgica</i> (1992) Vol. 115, 149-151				
	34.	Alliance Pharmaceutical Corp., "Imagent Product Summary," 5 pages (no date) <a href="http://www.allp.com/Imagent/IM_SUM.HTM">http://www.allp.com/Imagent/IM_SUM.HTM</a>				
	35.	BRANNON-PEPPAS, LISA, "Polymers in Controlled Drug Delivery," <i>Medical Plastics and Biomaterials</i> (1997) pp. 34-44				
	36.	BRAVERMAN, M.H. AND TAWES, R.L. EDS., "Upjohn Gelfoam[R] Sterile Sponge and Sterile Powder advertisement," <i>Surgical Technology: International Developments in Surgery and Surgical Research</i> (1992) 3 pages				
	37.	BURBANK, FRED AND FORCIER, NANCY, "Tissue Marking Clip for Stereotactic Breast Biopsy: Initial Placement Accuracy, Long-term Stability, and Usefulness as a Guide for Wire Localization," <i>Radiology</i> (1997) Vol. 205, No. 2, pp.407-415				
	38.	CLARKSON, P.: "Sponge Implants for Flat Breasts," <i>Proceedings of the Royal Society of Medicine</i> , Vol. 53 at 880-881 (1960)				

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INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	3	of	4	Attorney Docket No.	032,290-092
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## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s) volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	39.	COHESION TECHNOLOGIES, INC., "Business Summary," (11/19/1999) 3 pages, <a href="http://www.cohesiontech.com">http://www.cohesiontech.com</a>	
	40.	DAVOL, INC., Clotting Power: Hemostasis Products Catalog (date and website unknown) 2 pages	
	41.	DUFRANE, P. et al: "Prebiopsy Localization of Non-Palpable Breast Cancer," Journal Belgede Radiologie (October 1, 1990) Vol. 73, No. 5	
	42.	ETHICON HOME PAGE, "Ethicon: Wound Closure," (1998) 1 page, <a href="http://www.eosinc.com">http://www.eosinc.com</a>	
	43.	FOURNIER et al: "Experimental Studies and Preliminary Clinical Trial of Vinorelbine-loaded Polymeric Bioresorbable Implants for the Local Treatment of Solid Tumors", Cancer Research 51, pp. 5384-5391, October 1, 1991	
	44.	FREIHERR, GREG, "Biotech Devices Promise Benefits in Wound Repair and Surgery," Medical Device & Diagnostic Industry Medicine (1997) 6 pages, <a href="http://www.devicelink.com">www.devicelink.com</a>	
	45.	HACHISU, et al., "Endoscopic Clip-Marking of Lesions Using the Newly Developed HX-3L Clip," Surgical Endoscopy (1989) Vol. 3, pp. 142-147	
	46.	HOFMANN et al: "Biodegradable Implants in Orthopaedic Surgery - A Review on the State-of-the-Art," Clinical Materials; Vol. 10, 1992; pp. 75-80	
	47.	HOFMANN, G.O.: "Biodegradable Implants in Traumatology A Review on the State-of-the-Art", Arch. Cathop Trauma Surgery, 1995, pp. 114: 123-132	
	48.	KATZ, JON AND SPERA, GABRIEL, "Biomaterials Research Focuses on Developing New Applications," Medical Device & Diagnostic Industry Magazine (1998) 8 pages, <a href="http://www.devicelink.com">www.devicelink.com</a>	
	49.	KUMAR, AJAY AND BIOCORE, INC., Collagen Facts (date unknown) 2 pages	
	50.	LEBOVIC, G.S., "Utility of a Radiolucent, Bioabsorbable Marker Following Percutaneous Excision of Breast Lesions," University of Florida 5th Annual Multidisciplinary Breast Conference (Feb. 14-17, 2000) Poster, 2 pages	
	51.	MIDDLETON, JOHN AND TIPTON, ARTHUR, "Synthetic Biodegradable Polymers as Medical Devices," Medical Plastics and Biomaterials Magazine (1998) 17 pages, <a href="http://www.devicelink.com">www.devicelink.com</a>	
	52.	PANGMAN, W.J. and WALLACE, R.M.: "The Use of Plastic Prostheses in Breast Plastic and Other Soft Tissue Surgery," The Western Journal of Surgery, Obstetrics and Gynecology at 508 (August 1955)	
	53.	PARKER, STEVE, "Steps in a Stereotactic Mammotome Biopsy," Publication by Sally Jobe Breast Centre, (date unknown) pp. 1-5	
	54.	Publication by Medical Plastics and Biomaterials (1997) p. 61	
	55.	Publication by Surmodics, Inc. (date unknown) 1 page, <a href="http://www.surmodics.com">http://www.surmodics.com</a>	
	56.	RaB BIOCHEMICALS, "Structure and Properties of Collagen," High Quality Biochemicals from Scientist to Scientist (date unknown) 1 page	

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	57.	STOREY, ROBSON AND WIGGINS, JEFFREY, "Design and Fabrication of Polyester-Fiber and Matrix Composites for Totally Absorbable Biomaterials," Medical Plastics and Biomaterials Magazine (1996) 6 pages, <a href="http://www.devicelink.com">www.devicelink.com</a>			
	58.	Surgical Fibrillar: Absorbable Hemostat (Oxidized Regenerated Cellulose), "Advances Hemostasis ... Layer by Layer," Publication by Ethicon, a Johnson & Johnson company, 6 pages, date unknown			
	59.	TISSEEL, "The First FDA-approved Surgical Fibrin Sealant," Tisseel VH Kit Fibrin Sealant (date unknown) 5 pages.			
	60.	TROVAN®: Electronic Identification Systems, "Trovan Transponders," (12/13/1999) 7 pages, <a href="http://www.trovan.com/transponders.htm">http://www.trovan.com/transponders.htm</a>			

Examiner Signature	Date Considered
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